

BIONIME

Blood Glucose Monitoring System Instructions for Use

Rightest™ GM100

Preface

Thank you for purchasing the **Rightest™** Blood Glucose Monitoring System. Please read this manual thoroughly before you begin testing. This manual provides all the information you need to perform the test correctly. It is very important that you test your blood glucose levels routinely in order to avoid any health complications. The **Rightest™** Blood Glucose Monitoring System has been thoughtfully designed to provide you with the most accurate and simplified testing system in order to make managing your diabetes easier than ever.

The **Rightest™** Blood Glucose Monitoring System is manufactured by Bionime Corporation and is supported by its authorized representatives. If you have any questions, please contact your authorized distributor, in the Canada please contact Customer Service at 1 (800) 964-8434 (Monday through Friday 8:00 AM to 5:00 PM PST).

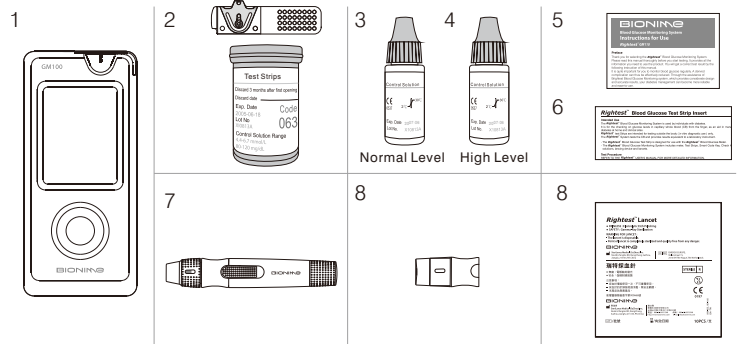
1. Intended Use

The **Rightest™** Blood Glucose Monitoring System is intended for in vitro diagnostic use (outside the body) for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the fingertip, palm or forearm. It is indicated for self-testing by persons with diabetes in the home or by healthcare professionals in healthcare facilities. Coding is not required with the GM100 meter. The test provides plasma equivalent results. It is not intended for the diagnosis of or screening for diabetes mellitus. It is not intended for use on neonate blood samples. Alternate site testing (palm or forearm) in this system can be used only during steady-state blood glucose conditions.

You may consult your healthcare professional for instructions on how to use the system correctly. Our customer support staff is available to help assist you as well.

2. Materials Included

1. **Rightest™** Meter
2. **Rightest™** Test Strips (0/10/25 pcs)
3. **Rightest™** Control Solutions (Normal Level)
4. **Rightest™** Control Solutions (High Level)
5. **Rightest™** Instructions for Use
6. **Rightest™** Blood Glucose Test Strip Package Insert
7. **Rightest™** Lancing Device
8. Clear Cap
9. Disposable Sterile Lancets (10pcs)
10. Instruction for the lancing device
11. Log Book
12. Warranty Card + Emergency
13. CR2032 Battery (Inserted into the meter)
14. Carrying Case



3. The Rightest™ Meter

Test Strip Port

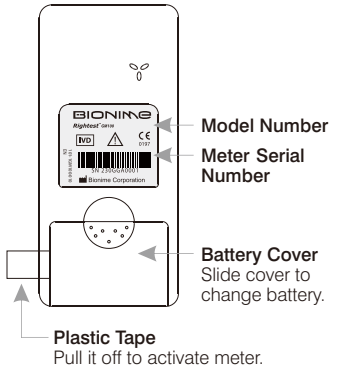
Insert test strip here until you hear a click.

Display Window

Shows test results, messages and related information.

Main Button

Press to turn on/off. Switch function screens or enter setting mode. (There will be a power-off period during this process.)



4. Precautions

- Before using the **Rightest™** System to test your blood glucose, please read all the instructions and practice performing a test including a quality control test.

- Please perform a quality control test regularly to make sure the test results are accurate.
- The **Rightest™ GM100** Blood Glucose Meter can only be used with the **Rightest™ GS100** Blood Glucose Test strips. Strips from other manufacturers or brands will not work with your meter and should not be used.
- The **Rightest™** Blood Glucose Monitoring System is intended for self-testing. It should not be used to diagnose diabetes mellitus.
- **Rightest™** Blood Glucose Monitoring System has not been validated for use on neonates. Therefore, it's not intended for use on neonates.
- This meter can be only tested with capillary whole blood. Do not use arterial blood.
- Wait 30 minutes before performing a test if you have moved the meter to a location with a significant change in temperature.
- Dispose of used batteries properly.
- Please note the meter kit contains small parts like test strips which could result in a choking hazard for children.
- Prevent water from entering the meter. Never immerse the meter or hold it under running water.
- The minimum blood sample size for testing is 1.4µL : (●)

Sample Size Example

1.0µL	1.4µL	2.0µL	3.0µL	4.0µL
●	●	●	●	●

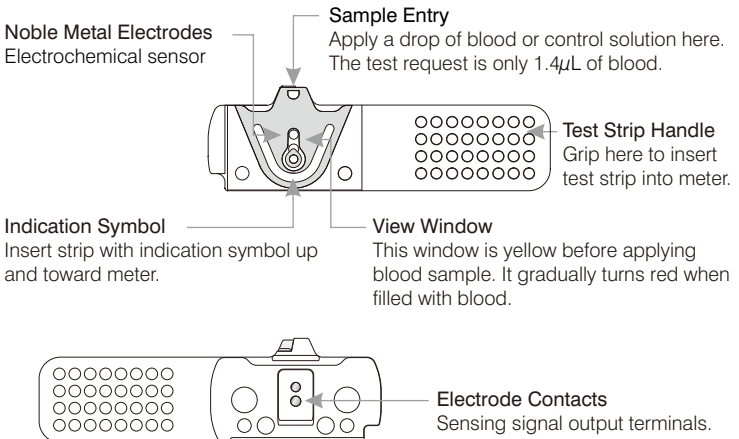
Please take a minimum of 1.4µL to run the test on your meter. Blood sample size above 4.0µL might contaminate the test strip port. Blood sample size below 1.4µL might cause inaccurate test result or might not start on meter measurement. In this case, repeat the test with a new test strip.

PRECAUTION

The unit of measurement should be fixed to " mmol/L ".

5. The Rightest™ GS100 Test Strip


Rightest™ GM100 is designed for use with **GS100** strip only. Please note that the use of other test strips might cause unexpected damage or produce inaccurate test results.



PRECAUTION

- Re-cap the test strip vial immediately after removing a test strip.
- Do not reuse test strips.
- Do not use expired test strips.
- Record the date when opening a new vial of test strips. Discard the vial 3 months after the date of opening.
- Store the test strips in a cool and dry location. Do not expose to direct sunlight or heat.
- For detailed information, please refer to the **Rightest™ GS100** Test Strip Package Insert.

6. Battery Installation

Your meter comes with one CR2032, 3volt, battery installed. One new battery will provide power to perform about 1000 tests under normal use. Before using it, please pull off the plastic tape and press the main button to activate the meter. The low battery symbol "  " will keep appearing on your display if your battery runs low. Please keep spares on hand and replace the battery soon when a battery symbol appears.

1. Turn the meter over. Press and push battery cover to open.
2. Install the battery. Be sure to put battery in correct direction.

3. Slide the battery cover back until it snaps into place.
4. The meter performs a self-test and all symbols on the display will blink.
5. Press any button to exit the self-test and enter Setting Mode.
6. Set the time and date when the batteries are replaced. See Setting the Date, Time and Unit section. Prior test results are still stored in the memory.

PRECAUTION

- Danger of explosion exists if the battery is installed incorrectly .
- Please follow your local and state guidelings when disposing of your used batteries.

7. Setting Up Your Meter

You can enter setting mode using either of the following options:

1. Reload battery

After removing the battery, please press the button several times until the screen goes blank, then follow the battery installation steps to load battery. The meter will do self test. Press the main button to close the test and enter Setting Mode.

2. With Battery inserted

Press the main button first to turn on the meter. Then press and hold the main button for 5 seconds (the meter will be turned off during this period, please keep pressing) until you hear a beep, indicating you have successfully entered Setting Mode. The display screen will show setting data.

NOTE

- When initially entering the setting mode, if you press and hold the main button for 2 seconds, the screen display will turn off. Don't stop pressing the button. Keep pressing the main button until you reenter the setting mode.
- Pressing and immediately releasing the main button allows you to change individual settings. Pressing and holding the main button for 2 seconds while in the setting mode confirms your settings.
- Holding the main button while in the setting mode for more than 5 seconds will exit settings.

1. Year setting

With the year format blinking, press the main button to adjust it. Then hold the same button for 2 seconds to confirm. It will shift to next digit for setting. Repeat the above action until the year setting is completed. Then it will move to month setting.

2. Month setting

With the month blinking, press the main button until the current month appears. Then hold the same button for 2 seconds to confirm it and move to day setting.

3. Day setting

With the day blinking, press the main button to adjust it. Then hold the same button for 2 seconds to confirm. It will shift to next digit for setting. Repeat the above action until the day setting is completed. Then it will move to time format setting.

4. Time format 12/24H selection

With the time format blinking, press the main button to adjust it. Then hold the same button for 2 seconds to confirm it and move to hours setting.

5. Hour setting

With the hour blinking, press the main button until the current hour appears. Then hold the same button for 2 seconds to confirm it and move to minute setting.

6. Minute setting

With the minute blinking, press the main button to adjust it. Then hold the same button for 2 seconds to confirm. It will shift to next digit for setting. Repeat the above action until the minute setting is completed. Then it will move to average-day setting.

7. Average-day setting

With the number " 1, 7, 14, 30 " blinking, press the main button for the days of the average you would like to read. Then hold the same button for 2 seconds to confirm it and move to measurement unit setting.

8. Ending setting

After confirm the measurement unit, you'll hear a sound of " beep ". All the settings are saved and completed and will return to time screen.

NOTE

- The meter will automatically shut-off after 2 minutes if it is not in use.
- If you would like to exit the setting mode, press and hold the main button for more than 5 seconds. The current settings will be saved.

Turning on /off the Meter

1. Auto Power off

The meter will automatically shut-off after 2 minutes if it is not in use.

2. Manual Power off




The meter will shut-off if you press and hold the main button for a couple seconds.

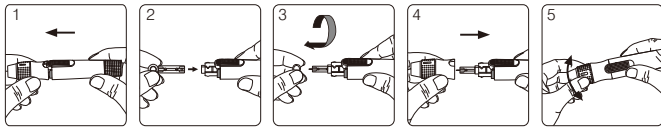
3. How to turn on your Meter

- 1) Press the main button.
- 2) Insert a test strip.

8. Performing a Blood Test

The **Rightest™** blood glucose monitoring system gives you an opportunity to obtain blood samples from fingertip, palm or forearm.

1. Pull off the depth adjustable cap.
2. Insert a new disposable lancet firmly into lancet carrier.
3. Twist off and set aside the protective cover of the disposable lancet.
4. Replace the depth adjustable cap.
5. Choose a depth of penetration by rotating the top portion of the depth adjustable cap until the setting depth matches the window. Settings are based on skin type "  " for soft or thin skin; "  " for average skin; "  " for thick or calloused skin.



6. Hold the hub in one hand and pull on the plunger in the other hand. The device is now loaded. Release the plunger, it will automatically move back to its original position near the hub.
7. Wash your hands with warm soapy water and dry thoroughly.

8. Take one strip from the vial. Re-cap the vial immediately.

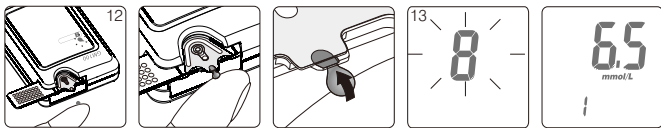
9. Insert the strip into the strip port on meter with the indication symbol facing up.

10. Add the blood sample when you observe the flashing blood sample indicator.

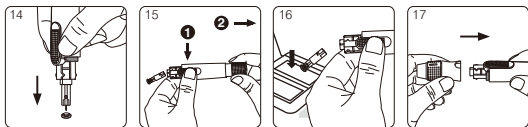
11. Place the lancing device against the pad of your fingertip and press the release button. The best puncture sites are on the middle of fingers. Press the release button.

12. Touch and hold the drop to the edge of sample entry until you hear a " beep " and the view window is totally filled with blood. If the view window is not totally filled with blood or the test does not start. Please discard the test strip and repeat the test with a new test strip.



13. The meter will commence counting down. After 8 seconds, the test result will appear.



14. Pull off the depth adjustable cap. Without touching the used disposable lancet, stick the lancet tip into the protective cover.
15. Hold the release button in one hand and pull on the plunger in the other hand. This will safely eject the used disposable lancet.
16. Discard the used disposable lancet into an appropriate puncture-proof or biohazard container.
17. Replace the depth adjustable cap after finishing the test.



PRECAUTION

- For more information on how to install the clear adjustable cap, please read the instruction manual for the lancing device.
- Use caution when loading the lancet.
- Do not touch your blood drop to the sample entry on the strip until you see the "  " appear. The meter is performing an internal test and will display "  " and " **Error** " if you apply blood too soon.
- Do not perform the blood glucose test at temperatures below 10°C (50°F) or above 40°C (104°F), below 10% or above 90% relative humidity.

Alternative site testing-palm or forearm blood sampling

1. Using the clear cap, follow the above listed steps 1 through 4.
2. Massage the puncture area of palm or forearm for a few seconds.
3. Immediately after massaging the puncture area, press and hold the lancing device with the clear cap against palm or forearm.
4. Then press the release button.
5. Continue holding the lancing device against palm or forearm and gradually increase pressure for a few seconds until the blood sample size is sufficient.

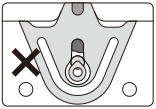
PRECAUTION

- Blood samples obtained from alternate sites may yield varied results when your blood glucose level is rapidly changing. For example, immediately after having a meal, drink, a dose of insulin or after exercising. In these cases, only fingertip blood should be used.

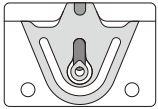
- DO NOT test on the palm or forearm if you are testing for hypoglycemia (Low blood glucose).
- Fingertip samples can show the rapid change of glucose faster than palm or forearm samples.
- Some lancing devices may not provide enough blood sample when obtaining samples from alternate sites. Please ensure that the lancing device is designed for alternate site testing, preferably with a clear cap.

9. View window appearance

Observe the view window area of the test strip to ensure that enough blood sample has been provided. Insufficient sample volume may yield incorrect results. If insufficient blood was provided, discard test strip and repeat the test with a new test strip.



Insufficient blood sample



Enough blood sample

- PRECAUTION**
- Check the expiration date printed on the package every time you use a strip. Do not use expired test strips.
 - Use each test strip immediately after removing from the vial.
 - Do not reuse test strips.
 - Wait 30 minutes before performing a test if you have moved the meter to a location with a significant change in temperature.
 - Place the blood drop only on the sample entry of the strip.
 - Do not drip or inject the blood sample directly by syringe to the entry port of test strip. Doing this might contaminate the meter or cause damage and is strongly not recommended.



Blood glucose test results are shown as mmol/L. If your blood glucose result is unusually high or low, or if you question your testing results, repeat the test with a new test strip. You can also run a Quality Control Test with **Rightest™** Control Solutions to check your meter and strip. If the test result still remains unusually high or low, contact your healthcare professional immediately.

If you are experiencing symptoms that are not consistent with your blood glucose test results and you have made sure to follow all steps of this instruction, contact your healthcare professional immediately.

The **Rightest™** Meter displays results between 1.1 and 33.3 mmol/L. If your test result is below 1.1 mmol/L, " **L_o** " will appear on the screen. Please repeat test with a new test strip. If you still get " **L_o** " result, you should immediately contact your healthcare professional.



If your test result is above the high end of the system's detection range 33.3 mmol/L, " **H_i** " will appear on the screen. Please repeat test with a new test strip. If you still get " **H_i** " result, you should immediately contact your healthcare professional.



10. Recalling Test Result & Average

The **Rightest™** meter is able to store 150 test results with time and date automatically. If your meter has stored 150 results, which is the maximum memory of the meter, the newest test result will replace the oldest one. To recall your test memory, start with the meter without test strip inserted.

1. Press the main button to switch the screen to memory function, you will see " **mem** " symbol on the upper right corner of the screen. It will show the latest testing result with time and date. The latest result is with sequence number, " 1 ".
2. Under the memory screen, use the main button to review all previous results with date and time. You will see results from the most recent (Sequence no, " 1 ") to the oldest (Sequence no, " 10 ") on the bottom left corner of the screen.
3. The **Rightest™** meter provides you several average test results. You can view 1-day, 7-day 14-day or 30-day average of test results depending on which one you've chosen in setting mode for better blood monitoring of your blood glucose.
4. Press the main button until the "AVG" symbol appears on the upper left corner of the screen. You will see 1-day, 7-day, 14-day or 30-day average of test results depending on which one you've chosen in setting mode.
5. The number shown on the bottom left corner means how many test results are calculated.
6. The " **L_o** ", " **H_i** " results, the control solution results, the non - average test results and the test result made out of normal temperature range (<10°C, >40°C) are not calculated in the average.



- PRECAUTION**
- You have to set the time and date to activate the average function.

11. Quality Control Test

To ensure that your **Rightest™** Blood Glucose Monitoring System is working properly, it is recommended that you perform a Quality Control Test.

1. Entering Control Solution mode

Insert the test strip into the test strip port area of the meter. When the blood drop symbol flashes, press and hold the main button for 5 seconds or more until the " **CS** " symbol appears. The CS symbol indicates that you have successfully entered the control solution testing mode.

2. Control Solution Test

A control solution test ensures that the meter and test strips are functioning properly together. Once you enter control solution mode, you are ready to perform a control solution test.

When Should I perform a Quality Control Test?

Before performing a blood glucose test with your meter for the first time.

When you open and start using a new test strip vial.

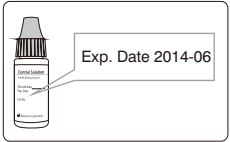
When your meter is dropped or splashed with liquids.

Whenever the test result is inconsistent with your symptoms.

Whenever you want to check if your system is working properly.

Whenever you want to practice testing and check correct procedure

- PRECAUTION**
- Each time you open a new bottle of Control Solution, write the discard date on the label. Control Solution is good for 3 months after opening the bottle, or until the expiration date printed on the label, whichever comes first.



- PRECAUTION**
- If you want to purchase new normal or high level control solution, please contact your authorized Bionime representative.

Understanding Control Test Results

Your control solution test results should fall within the control solution range. That means your **Rightest™** System is working correctly.

- Control Solution Range**
- 4.4-5.9 mmol/L**

Example of control solution range printed on your test strip vial label.

Contact your authorized Bionime Representative or Bionime Customer Service if the results continue to be outside the control solution range. Do not use the **Rightest™** System to measure your blood glucose levels if the results are not within the control solution range.

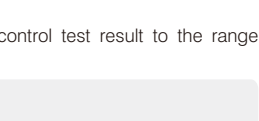
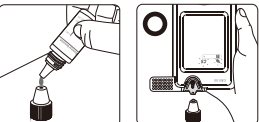
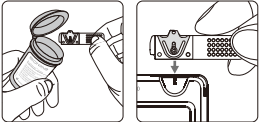
Reasons Control Solution may be out of range :

- The Control Solution has expired (3 months after opening).
- Test Strip has expired.
- The cap on the test strip vial was not closed properly.
- Incorrect Test Procedure (i.e. insufficient sample).
- Meter malfunction.

12. Performing a Quality Control Test

Use with Control Solution

1. Take one test strip from vial and re-cap the vial immediately.
2. Insert the test strip with view window, facing up, into test strip port.
3. While the blood drop symbol flashing, press and hold the main button for over 5 seconds until the " **CS** " symbol appears.
4. When the blood drop symbol flashes, press and hold the main button for 5 seconds or more until the " **CS** " symbol appears.
5. Shake the bottle of control solution well before opening the cap. Then open the cap and put it on the table.
6. Drip a drop of control solution on the top of the cap.
7. Gently touch sample entry of the strip with the control solution on the top of the cap.
8. The meter will commence counting down. After 8 seconds, the test result will appear.
9. Tightly replace the cap on the control solution bottle.
10. The control solution result appears. Compare your control test result to the range printed on the test strip vial label.



- Do not drip or add the control solution directly to the test strips as contamination or interference may occur.



- Do not touch the Control Solution. If Control Solution gets on your hands, wash thoroughly with soap and water.

Maintenance

Keep your meter and test strip free of dust, water or any other liquid. Store the meter in the carrying case when not in use. If meter is dropped or damaged, perform a quality control test using the control solution before testing your blood glucose level.

Cleaning your Meter

Clean the outside of the meter with a damp cloth and mild soap/detergent. Do not expose the test strip port to water.

13. Error Message and Trouble Shooting

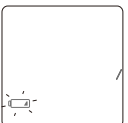
- Er1** - The inserted strip has been used or damaged. Please use a new test strip from vial.




- Er2** - Meter has malfunctioned. Perform a quality control test or reinstall the battery to see if the meter works properly. If error screen still appears, contact Bionime Customer Service.

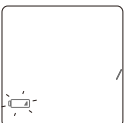



- Er3** - Signal transmission is disrupted, repeat the test.



You can still perform a test

1. The "  " symbol is blinking when the battery power is low. Please change battery as soon replace the battery as soon as possible. You can still do the test.




2. The "  " and " **Error** " symbols are blinking when the battery is too low. The meter can not perform a test. Please change the battery immediately.

3. After changing the battery, perform a quality control test.

Temperature Error

In order to get an accurate test result, perform testing between 10~40°C (50~104°F).

1. When the ambient temperature is 0~9°C (32~48°F) or 41~50°C (106~122°F) the "  " a warning symbol will appear. You may still perform the test, however the results are for your reference only since the extreme temperature might have affected the result. Repeat the test 30 minutes after you have entered an area with the correct operating temperature range. (10~40°C or 50~104°F)




2. When moving from an area with a temperature outside the operating range to one that is within the operating range, wait for 30 minutes before performing a test.



3. Do not perform a test when the temperature is below 0°C (32°F) or over 50°C (122°F). An " **Error** " symbol will appear. Move to a different location or adjust the temperature to 10~40°C (50~104°F) and repeat the test after 30 minutes.



Sampling Error

Do not add sample before the "  " appears. The Rightest Meter is performing an internal quality control check. Please remove the test strip and insert a new test strip.



Meter Malfunction


If your meter will not power ON, please perform the following:

1. Open the battery cover, take out the battery.
2. Wait for 5 minutes and reload the new battery.

The meter should power ON as usual after this. If not, please contact your Bionime authorized distributor or contact Bionime Customer Service.

Specification

Measurement Technology	Oxidase Electrochemical Sensor
Sample	Capillary whole blood
Minimum Sample Volume	1.4 microliter
Measuring Range	1.1-33.3 mmol/L
Test Time	8 seconds

Memory Capacity	150 blood glucose test results with date and time
Power Saving	Turn off automatically after 2 minutes no use Press the "  " button for 2 seconds.
Operating Temperature	10 ~ 40°C (50 ~ 104°F)
Operating Relative Humidity	10 - 90%
Hematocrit	30 - 55%
Power Supply	one CR2032 battery
Battery Life	About 1000 tests
Meter Dimension	95.0 mm x 43.8 mm x 13.0 mm
Meter Weight	43.0 g with battery
Monitor	LCD display
Display Area	39.0 mm x 38.0 mm
Meter Storage Conditions	-10 ~ 60°C (14 ~ 140°F)
Test Strip Storage Conditions	4 ~ 30°C (39 ~ 86°F), < 90% relative humidity

Limitations

- **Rightest™** Blood Glucose Test Strips are designed for use with capillary whole blood samples. Do not use serum or plasma samples.
- Inaccurate test results may be obtained at high altitudes. Approximately 10,000 feet (3048 meters) above sea level.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- **Rightest™** Blood Glucose Monitoring has not been validated for use on neonates.
- Results may be invalid when testing with samples containing unusually high concentrations of:
 - Uric acid \geq 0.40 mmol/L
 - Cholesterol \geq 13 mmol/L

- NOTE**
- Acetaminophen, Ascorbic acid (Vitamin C), Dopamine, Ibuprofen, Salicylic Acid, Tetracycline, Bilirubin-conjugated, Creatinine, Triglyceride, Maltose, Xylose, Galactose and Lactose (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results (the bias of interference is below 10%). However, abnormally high concentrations of these interferents in blood may cause inaccurate results.
- In addition when blood glucose concentration drops below 3.9 mmol/L, the bias of interference with the presence of L-dopa and methyl-dopa may be slightly higher than 10%.

Customer Service

Bionime is committed to providing you with the highest quality of Customer Service. If you have any questions, please contact your authorized distributor, in the Canada please contact Customer Service at 1 (800) 964-8434 (Monday through Friday 8:00 AM to 5:00 PM PST). Or e-mail at info@bionime.com

For 24 hour assistance please contact your healthcare provider. Review the instructions to ensure that the correct testing procedure has been followed.

Warranty

Bionime Corporation warrants that your **Rightest™** Meter will be free from defects in materials and workmanship for five years from the date of purchase.

This warranty does not apply to the performance of a **Rightest™** Meter that has been altered, misused, tampered with or abused in any way.

This warranty applies only to the original purchaser of the meter.

Please complete and return the enclosed warranty card to Bionime authorized representative.

Different models have different specifications. Some of the models are not included with the warranty card.

Expected values for normal glucose level ⁽¹⁾		Status	Range (mmol/L)
Fasting			3.9 – 5.5

References

- 1) Diabetes Information - American Association for Clinical Chemistry (AACC) [Electronic Version] Retrieved February 08, 2006 from www.labtestsonline.org/understanding/analytes/glucose/test.html

Parts of Critical Component

Blood Glucose Meter, Test Strip, Control Solution and Lancing Device

Manufacturer: Bionime Corp.

Product complied with In Vitro Diagnostic Medical Device Directive 98/79/EC. (CE0197)





EU Rep: Klaus Ellensohn, Tschuetschgasse 8, 6833 Klaus / Vlbg., Austria

Disposable Sterile Lancets

Manufacturer: SteriLance Medical (SuZhou) Inc.

EU Rep: EMERGO EUROPE, Molenstraat 15, 2513 BH The Hague, The Netherlands.

(CE0197)

IVD	For in vitro diagnostic use		Manufacturer	LOT	Lot number
	Use by		Temperature limitation		Do not reuse
STERILE	R	Method of sterilization using irradiation		EC REP	EU Representative

BIONIME



BIONIME CORPORATION

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EC REP

Klaus Ellensohn
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Identifier of the device, number 53352.
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